Collaboration between the medical profession and industry

Guidelines issued by the Swiss Academy of Medical Sciences (SAMS)

Approved by the Senate of the SAMS on 29.11.2012.

These Guidelines supersede the Guidelines on "Collaboration between medical professionals and industry" issued by the SAMS in 2006.

The German text is the authentic version.

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"A useful criterion in determining acceptable activities and relationships is: would you be willing to have these arrangements generally known?"

"Physicians and the Pharmaceutical Industry", Guidelines of the American College of Physicians, 1990

Preamble

There is a long tradition of collaboration between physicians and industry, which is essentially in the interests of good healthcare and frequently helps to increase scientific knowledge. However, such collaboration may give rise to conflicts of interest, dependencies or even, in exceptional cases, conflicts with the law.

Conflicts of interest can be of a financial, psychological or social nature. They do not arise from particular kinds of action or omission. Nor is it decisive whether a person feels influenced in a certain situation.

Recommendations on "Collaboration between the medical profession and industry" were first published by the SAMS in 2002. In 2005, these were partly revised and reissued as Guidelines, which came into effect in 2006. These Guidelines were then incorporated into the Code of Conduct of the Swiss Medical Association (FMH). In addition, the SAMS established an Advisory Committee on collaboration with industry¹. Since 2007, this committee has overseen the practical implementation and interpretation of the Guidelines.2

In practice, further points requiring clarification and a number of gaps were identified. The SAMS therefore decided to revise the Guidelines in 2012. In particular, apart from the revision and expansion of certain sections, a section on consultancy activities was added.

The Guidelines are applicable to relations between physicians and healthcare suppliers – in particular, companies in the pharmaceuticals, medical devices and IT sectors. They are intended to promote appropriate management of conflicts of interest which may arise when compensation (financial or otherwise) is provided in return for physicians' services. The aim of the Guidelines is not to prohibit, but – by recommending appropriate behaviour for everyday professional activities – to promote objectivity, quality and transparency, to prevent dependencies and to facilitate the management of conflicts of interest.

The SAMS is well aware that such Guidelines can never offer solutions directly applicable to every individual case. In practice, all parties are to apply and comply with the spirit of the Guidelines to the best of their ability. The medical profession and industry are therefore called on, as partners, to organize – and where necessary adjust – their interactions accordingly.

Principles

It is crucial that, in any conflict of interest, the parties proceed in accordance with the following principles:

- Principle of separation: Physicians' dealings with patients in particular must be independent of any material benefits promised or received. The processes and procedures in question are to be strictly separated.
- Principle of transparency: Any material benefits promised or received, especially where nothing is provided directly in return, must be disclosed.
- Principle of equivalence: Benefits must not be disproportionate to the services provided in return.

¹ http://www.samw.ch/de/Portraet/Kommissionen/Beratende-Kommission.html
2 Swissmedic, the authority responsible for enforcement, published in the *Swiss Medical Bulletin* a supplementary contribution on its interpretation of the prohibition on promises and acceptance of material benefits under Article 33 of the Therapeutic Products Act (available in French www.bullmed.ch/docs/saez/archiv/fr/2007/2007-39/2007-39-416.PDF and in German www.saez.ch/docs/saez/archiv/de/2007/2007-39/2007-39-416.PDF).

- Principle of documentation: All services must be agreed in writing. The nature of the services and
 the compensation are to be specified in detail, together with the purpose of the services to be
 provided. If such agreements concern employees of healthcare institutions, they are to be
 approved by the employer or by the line manager responsible.
- "Two-pairs-of-eyes" principle: It should not be permissible for important decisions to be taken by a single individual. The aim is to reduce the risk of errors and abuses. All contracts and financial transactions are to be signed by two people at each institution.
- Principle of separation of accounts: Third-party funding for research and teaching is to be managed separately in each case. All such transactions must be transparent and auditable.

In the collaboration of physicians with industry, disclosure is necessary as a first step towards the appropriate management of any conflicts of interest. For physicians in research, hospital and practice settings, this is not only a matter of legal requirements but also of professional ethics. By adopting guidelines on its own initiative, with a code of conduct clarifying and supplementing legal regulations, the medical profession underlines its desire for independence and credibility.

I. Clinical research

Introduction

The aim of clinical research is to gain a scientific understanding of human diseases and to translate this knowledge into practice through the development of effective methods for diagnosis, prevention and treatment. Clinical research is a prerequisite for any advances in medicine.

Clinical research is a complex process, involving several stages and extending over many years, for the development of new, improved and safer preventive, diagnostic and therapeutic products and procedures; it is carried out at universities, hospitals and research institutes and in practice settings. The conduct of clinical research is governed by strict scientific, ethical and legal requirements, primarily designed to ensure the protection of trial subjects (see "Relevant provisions and authorities" in the Appendix).

In many areas, collaboration of clinical researchers with industry or with contract research institutes is a key requirement for innovative research. However, the prospect of obtaining financial benefits or recognition thanks to a clinical trial or its results may lead researchers to act inappropriately in the planning, conduct or analysis of a trial. The applicable regulations³ designed to ensure the quality of research projects and to protect the trial subjects concerned therefore need to be supplemented by guidelines that promote the objectivity of research, help to prevent dependencies and facilitate the management of conflicts of interest.

Guidelines

1. Clinical research is guided by scientific and ethical standards.

Clinical research must comply with current scientific and ethical requirements, legal regulations and the internationally recognized principles of Good Clinical Practice (GCP)⁴. Researchers are legally required to have GCP training corresponding to their function and responsibilities within the research project.

2. Institutions regularly evaluate the quality of the clinical research they carry out.

The scientific quality of clinical trials is to be assessed on the basis of their originality and methodology, as well as the results obtained (including disclosure of negative results). Also to be taken into account are the quality of the publication and the importance of the findings.

³ Human Research Act (HFG), Therapeutic Products Act (HMG), Good Clinical Practice (GCP) guidelines.

⁴ In addition, according to Art. 9 para. 2 let. I of VKlin, the investigator must have the necessary training or experience in GCP.

3. All clinical trials are recorded in a registry accessible to the public.

The aim of registration, in particular, is to ensure that:

- the results are fully and correctly published,
- changes to the study protocol are scientifically comprehensible and justified, and
- post hoc changes to the study protocol which are not in accordance with GCP can be identified.

The registry should provide information on the relevant parameters of a trial⁵.

4. The researcher responsible and his/her co-workers have no financial interest in the trial or its results.

The researchers involved in a trial are to disclose to the institution where they work any financial interests associated with their participation. In particular, the researcher responsible for a trial or his/her co-workers must not at the same time be proprietors, partners, board members or major shareholders of a company that uses the procedure or manufactures or markets the product under investigation. Any justified exceptions to this rule must be approved by the institution where the researchers work.

5. The conduct and financing of clinical trials are governed by a contract.

Every trial conducted on behalf of and financed by a third party (i.e. a sponsor) is to be governed by a written contract. The contract is to be signed by the researcher responsible and, where appropriate, by the competent representative of the institution where the researcher works, and also by the sponsor.

The following points are to be specified in the contract:

- the clinical trial which is the subject of the contract;
- the various parties' obligations and responsibilities;
- the parties' respective contributions in the conduct of the trial;
- the compensation provided, the level of which should be commensurate with the services actually performed;
- the investigator's unrestricted access to all data relevant to the conduct of the trial and the protection of the trial subjects concerned;
- access to statistical analyses;
- the obligation to publish the results of the trial or make them accessible to the public;
- the assurance of the investigator's freedom to publish;
- the conditions under which, if appropriate, the trial can or must be discontinued;
- indemnification for liability in the event of damage arising from the clinical trial;
- rights to the subsequent use of data or trial results.

⁵ Registration of clinical trials will be a legal requirement with the entry into force of the Human Research Act (HFG) and the related ordinances.

6. Payment for trials conducted at institutions is made to institutional accounts for third-party funds.

All financial contributions from sponsors in connection with clinical trials are to be credited to dedicated accounts. Access to these accounts is controlled by the institution (university, department, hospital, foundation, etc.) for which the investigator works.

7. When a scientific study is published, authorship is limited to those researchers who have made a substantial contribution.

Individuals are only to be named as authors of a publication if they played a significant part in planning, data collection, analysis and/or preparation of the manuscript. If third parties (medical writers) contribute to the publication, their names are to be listed and any affiliations with an industrial or other sponsor are to be disclosed. Guest authorship is not permitted.

The involvement of ghostwriters not listed in the publication as third-party contributors is not acceptable.

8. Financial or material support provided for a trial is to be disclosed when the results are published or presented.

In publications reporting the results of a trial, the sponsor who financed the trial must be clearly indicated to readers in a note or footnote. This is also to be clearly indicated when trial results are presented at lectures, conferences and similar events; any interests which the authors may have are also to be declared.

9. The results of a trial must be interpreted independently of the interests of the party providing financial or material support.

When the results of a trial are interpreted in publications or at presentations, conflicts of interest are to be avoided. The investigator must therefore take particular care to ensure:

- that the desirable and the adverse effects of a product or procedure observed in the trial are accurately documented and critically discussed;
- that the cost/benefit ratio of the product or procedure investigated is presented as objectively as possible.

10. Researchers do not participate in the marketing of products which they have previously investigated.

Researchers responsible for or involved in a trial must not undermine their independence or credibility by participating in marketing campaigns for the product or procedure investigated.

II. Basic and postgraduate medical training and continuing medical education

Introduction

The number of diagnostic and therapeutic agents and procedures available to medicine is constantly growing. Basic and postgraduate training and continuing education for physicians needs to be continuously adapted to these developments. Continuing medical education (CME) should provide the participants with objective and balanced knowledge and skills which are useful and necessary for patient care; it is a prerequisite for appropriate medical practice.

The continuing medical education prescribed by law entails considerable additional costs for physicians. Apart from the costs of attendance, CME events involve a loss of working hours and income. The financing of these costs is not assured either for hospitals or for practising physicians. As the acquisition of new knowledge enriches medical practice, it is therefore also in the interest of the individual physician.

A substantial proportion of CME events are financially supported ("sponsored") or organized by the pharmaceutical industry and the medical devices sector (hereafter referred to as "industry" or "companies"). While this is now taken for granted by many physicians and institutions, it may give rise to dependencies or conflicts of interest. Accordingly, guidelines are also required for this area.

In basic and postgraduate medical training, the same considerations apply with regard to support provided by industry as for continuing medical education.

Guidelines

1. The application for accreditation of a CME event by the competent bodies (professional societies, cantonal medical associations, Swiss Institute for Postgraduate Training & Continuing Medical Education) is submitted by the physicians or medical committees organizing the event.

The organizer of a CME event is responsible for applying to the competent professional body for accreditation. Accreditation is only granted for CME events which fully comply with the present Guidelines. Events are to be guided by the aims specified in the CME Regulations (FBO/RFC)⁶ of the Swiss Institute for Postgraduate Training & Continuing Medical Education (SIWF/ISFM)⁷ and the professional societies' CME programmes.

2. Accreditation is only granted for CME events if the content and programme is defined or decisively shaped by physicians or medical committees.

In particular, the following conditions apply:

- The event organizers are organizations, institutions or individuals with expertise in the area concerned, and not industry.
- CME events are to be financed by participants' fees and the host institution. If additional
 financial support is required, sponsorship should be sought from a number of different (mutually
 independent) companies.
- As a rule, a fee for participation is to be charged. Fees need not be charged for shorter (half-day) CME events.
- Agreements between event organizers and sponsors are to be made in writing.
- The organizers, not the sponsors, are to define the content and programme for the event and select the speakers. Satellite symposia organized by sponsors are to be designated as such, scheduled for non-prime times and not accredited as CME events.

⁶ Available in French www.fmh.ch/files/pdf6/fbo f.pdf and German www.fmh.ch/files/pdf6/fbo d.pdf.

www.fmh.ch/bildung-siwf.html

- Participants should be given the opportunity to evaluate CME events.
- Any accompanying programme is to be incidental to and must be clearly separated from the scientific/professional component.
- The approval of credits for a CME event must be settled before invitations are sent out.
 Invitations to CME events including wordings such as "Application for credits submitted" are not permissible. Applications for credits should be dealt with by the competent bodies within a period of four weeks.

To avoid unnecessary administrative effort, professional societies may grant global or advance accreditation to CME events regularly conducted by the societies themselves or by hospitals or hospital departments; in such cases, however, a written assurance that the CME events comply with these Guidelines is required from the professional society, hospital or hospital department concerned.

3. As far as possible, preventive, diagnostic and therapeutic options are presented in accordance with the criteria of evidence-based medicine and with due consideration for cost-effectiveness.

Topics should be discussed objectively according to the current state of scientific knowledge and from various perspectives (interdisciplinary approach). As a rule, diagnostic and therapeutic options should be presented in full and, as far as possible, in accordance with the criteria of evidence-based medicine (EBM).

4. If various effective agents, medical devices or procedures are available for prevention, diagnosis or treatment, they are to be compared as objectively as possible.

In presentations, medicines are generally to be referred to by their generic names⁸.

5. Funding obtained from sponsorship is credited to a dedicated account held by the event organizer (university, institution, foundation, professional society, regional medical association, etc.) and employed for the organization of CME events, remuneration of speakers and defrayal of their expenses.

Industry-supported CME events held in hospitals and lasting one or more days are to be approved by the competent body.

Finances are to be controlled by the event organizer. Budgets and accounts are to be made available to sponsors and professional societies on request.

6. Physicians attending CME events as listeners (i.e. not giving presentations, posters or talks, or chairing meetings, etc.) bear an appropriate share of the costs.

For the sake of their independence, physicians attending a CME event, or their employers, are to bear an appropriate share – generally at least a third – of the costs of participation, travel and accommodation.

It is not permissible for a sponsor to provide full or partial reimbursement of the costs borne by an attendee and/or compensation for indirect costs (loss of working hours or income).

Non-self-employed physicians who are offered financial support by a company to participate at an event are to inform their line manager of the level of support and the sponsor. For physicians in postgraduate training, invitations are generally issued to the institution, which then decides on participation.

The costs of additional hotel accommodation, travel or other activities not intrinsically related to the event itself are to be borne in full by the attendee or accompanying persons.

⁸ International Nonproprietary Names for pharmaceutical substances (INN)(www.who.int/medicines/services/inn/en/)

7. Speakers and organizers disclose any personal or institutional commercial interests, financial ties with the sponsor, consultancy activities undertaken for the sponsor, or research support received from the sponsor.

Speakers' fees should be appropriate.

All sponsors are to be listed in the programme and documentation for the event.

Speakers are to declare their interests in an appropriate manner to the event organizer, to the professional society and – before the start of their presentation – to attendees.

8. If medical faculties or their parent universities establish a teaching and/or research post (professorship) which is financed by companies or other third-party funding, they specify the fundamental conditions in writing.

In such cases, the independence of teaching and research is to be assured.

9. Medical faculties ensure that no inappropriate interactions occur between medical students and industrial companies.

In particular, faculties are to ensure that, in the course and in the broader context of their basic medical training, students are not unduly influenced by industrial companies through gifts or other material benefits or in other ways. In addition, they are to raise students' awareness of potential conflicts of interest arising from collaboration between the medical profession and industry.

10. Hospital physicians in management positions ensure that contacts between industry representatives and hospital staff take place within an institutional framework.

As a rule, contacts between industry representatives and hospital staff, especially assistant physicians, should take place on hospital premises. Physicians in management are to ensure that they are informed about such contacts and about the content of discussions.

III. Consultancy activities

Introduction

Physicians' services are enlisted when their expertise is required to address specific medical questions. Requests may be received from various parties – e.g. from a public authority wishing to publish recommendations on health behaviour, from an industrial company wishing to conduct research or launch a new product, or from a professional society wishing to elaborate guidelines. In such cases, there is always the potential for conflicts of interest.

Guidelines

1. When participation on an Advisory Board or similar body (cf. Glossary) is being considered, the need and justification for such consultancy should be examined.

In particular, the following points should be clarified:

- whether the purpose of the consultancy is clearly defined and justified; in particular, Advisory Boards for marketing purposes are to be avoided;
- the duration of and rationale for the consultancy;
- whether one has the necessary expertise to express a credible opinion on the matter in question;
- whether any conflicts of interest exist;
- on what criteria the selection (including the number) of experts is based.

Where appropriate, an invitation to serve on an Advisory Board is to be declined.

- 2. Consultancy services are provided on the basis of a contract, which documents in particular the nature, purpose and scope of the consultancy, the fee, the expert's independence and provisions concerning transparency.
- 3. The level of the fee agreed for participation on an Advisory Board or similar body should reflect the services provided.
- 4. Members of bodies responsible for the preparation of guidelines disclose any conflicts of interest at the outset and periodically thereafter; this information is published together with the guidelines.
- 5. A physician only participates in an observational study or an online survey if it seeks to address a relevant scientific question and is not a form of marketing.
- 6. Members of internal bodies responsible for institutional purchasing of therapeutic products must declare their interests.

In the event of foreseeable conflicts of interest, the member concerned should not be involved in decision-making.

7. Experts and "opinion leaders" do not allow themselves to be named as authors of publications to which they have not made a substantial contribution and for whose content they cannot fully vouch (no "guest authorship").

IV. Acceptance of payments in cash or in kind

Introduction

Article 38 of the Code of Conduct of the Swiss Medical Association (FMH) states that: "it is not permissible to accept gifts [...] or other benefits [...] from third parties which could influence the physician in his/her medical decisions and which go beyond customary tokens of appreciation."

This question is also covered by various legal provisions (Art. 33 Therapeutic Products Act, Art. 56 para. 3 Health Insurance Act, Art. 322^{ter} ff. Swiss Criminal Code; cantonal regulations). The following Guidelines are to be understood and observed as aids to implementation in practice.

Guidelines

1. Physicians in hospital, practice or research settings do not accept from industry any payments in cash or in kind which go beyond financially insignificant tokens of appreciation.

In public hospitals, the acceptance of payments in cash or in kind is governed by internal regulations. Within the institution, these specify which gifts are to be approved by, and which are only to be reported to, the line manager (e.g. by setting upper limits or elaborating a "white list").

For all major purchases and contracts, a joint signature is required ("two-pairs-of-eyes" principle). The acceptance of payments in cash or in kind and the institution's purchasing function are to be kept strictly separate.

All agreements on the acceptance of payments in cash or in kind above an internally specified limit are to be made in writing. These agreements also include a declaration that no (verbal or tacit) subsidiary agreements have been made. Also to be specified are the purposes for which funds paid into a donation account may be used. Access to this account is to be controlled by internal regulations.

2. Physicians make appropriate use of free samples.

Physicians should be aware that prescribing behaviour can be influenced by drug samples.

Advisory Board Body composed of physicians and other experts which provides advice on medical questions to a company or other organization. Also known, for example, as a Concept Board, Expert Panel, Executive Council or Round Table.

Basic medical training University education (studies)

Clinical research Research involving *trial subjects* or materials of human origin, i.e. involving contact with human beings (in contrast to basic research). Clinical research includes, for example, patient-focused research, epidemiological studies, outcomes research and health services research.

Clinical trial Research project in which persons are prospectively assigned to a health-related intervention in order to investigate its effects on health or on the structure and function of the human body. (This definition is taken from Art. 3 let. I HFG.)

CME events e.g. conferences, meetings of physicians for sharing of experiences ("quality circles"), online CME programmes.

Continuing medical education (CME) Ongoing updating and expansion of professional skills after the completion of *postgraduate medical training*; it is designed to ensure the quality of professional practice.

GCP Good Clinical Practice guidelines designed to protect *trial subjects* and to ensure the quality of clinical trial data.

Generic name International Nonproprietary Name (INN) given to a pharmaceutical substance.

Gifts Benefits offered in the absence of an agreement on services and with no purpose specified.

HFG (German abbreviation for) Federal Act on Research Involving Human Beings (Human Research Act).

HMG (German abbreviation for) Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act)

Institution e.g. university, hospital, network.

Medical devices Products, including instruments, apparatus, in vitro diagnostics, software and other goods or substances which are intended to have or are presented as having a medical use and whose principal effect is not obtained with a medicinal product (Art. 4 para. 1 let. b, HMG).

Medicinal products Products of chemical or biological origin which are intended to have or are presented as having a medicinal effect on the human or animal organism, in particular in the diagnosis, prevention or treatment of diseases, injuries and handicaps; blood and blood products are also considered to be medicinal products (Art. 4 para. 1 let. a, *HMG*).

Postgraduate medical training An activity of specified duration and content, which is subject to evaluation and is designed to expand the knowledge and skills acquired in the course of previous medical studies, in preparation for independent professional practice.

Sponsor Any person or organization assuming responsibility for the initiation, management or financing of a *clinical trial* (Art. 5 let. b, VKlin).

Sponsorship Financial support provided for an event, a project, a publication or other activities, not in return for services of equivalent value, but with a purpose being specified; this support may or may not be subject to conditions concerning disclosure.

Therapeutic products Umbrella term for medicinal products and medical devices.

Third-party funding Financial support made available to a person or an institution from an external source in return for agreed services (dedicated project financing) and which has the same value for both parties (in contrast to *sponsorship*).

Trial subjects Persons taking part in a *clinical trial*, who are either exposed to the therapeutic product under study or assigned to a control group (Art. 5 let. d, VKlin).

Relevant provisions and authorities

I. Clinical research

National and international regulations for the conduct of clinical trials:

Integrity in scientific research. Principles and procedures. Swiss Academies of Arts and Sciences, 2008.

www.akademien-schweiz.ch/en/dms/E/Publications/Guidelines-and-Recommendations/e Integrity.pdf

World Medical Association (WMA) Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (revised version, October 2008). www.wma.net/en/30publications/10policies/b3/

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use: Guideline for Good Clinical Practice https://www.ich.org/fileadmin/Public Web Site/ICH Products/Guidelines/Efficacy/E6 R1/Step4/E6 R1 Guideline.pdf

Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Biomedicine Convention) http://conventions.coe.int/treaty/en/treaties/html/164.htm

CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. www.consort-statement.org/consort-statement/

International Committee of Medical Journal Editors: Uniform requirements for manuscripts submitted to biomedical journals.

www.icmje.org/urm_full.pdf

Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors. New England Journal of Medicine 2004; 351:1250-1251 www.nejm.org/doi/full/10.1056/NEJMe048225

Drug regulatory authorities, legislation and other regulations:

Switzerland: Swiss Agency for Therapeutic Products (Swissmedic) www.swissmedic.ch

Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act; HMG)

www.admin.ch/ch/e/rs/c812 21.html

Ordinance of 17 October 2001 concerning Clinical Trials with Therapeutic Products (VKlin) www.admin.ch/ch/d/sr/c812 214 2.html

Ordinance of 17 October 2001 concerning the Promotion of Medicinal Products (AWV) www.admin.ch/ch/d/sr/c812 212 5.html

Federal Act on Research Involving Human Beings (HFG; adopted by Parliament on 30 September 2011; expected to come into force in mid-2013)

European Union: European Medicines Agency (EMA) www.ema.europa.eu/ema/

Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

Overview of pharmaceutical legislation:

http://ec.europa.eu/health/documents/eudralex/vol-1/index en.htm

Directive 2001/20/EC:

http://ec.europa.eu/health/files/eudralex/vol-1/dir 2001 20/dir 2001 20 en.pdf

US: Food and Drug Administration (FDA) www.fda.gov/

Good Clinical Practice in FDA-regulated clinical trials www.fda.gov/oc/gcp/default.htm

Industry codes of conduct:

Code of Conduct of the Pharmaceutical Industry in Switzerland (Pharma Code) of 4 December 2003 (including subsequent revisions)

www.sgci.ch/plugin/template/sgci/*/63768

Federation of Swiss Medical Devices Trade and Industry Associations (FASMED) Code of Business Conduct

www.fasmed.ch/de/info-center/publikationen/code-of-business-conduct-statuten.html?no cache=1&cid=2601&did=1876&sechash=47098dea

European Federation of Pharmaceutical Industries and Associations (EFPIA)

EFPIA HCP Code: EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals

www.efpia.eu/sites/efpiaweb.voxteneo.com/files/EFPIA%20Code_Promotion_HCP_-11.06.14 FINAL EDITING 07-08-11-mcp-20110630-002-EN-v1 0.pdf

Eucomed Guidelines on Interactions with Healthcare Professionals www.eucomed.org/key-themes/ethics

II. Basic and postgraduate medical training and continuing medical education

International recommendations and guidelines:

World Medical Association (WMA) Statement concerning the Relationship between Physicians and Commercial Enterprises (revised version, October 2009). http://www.wma.net/en/30publications/10policies/r2/

Canadian Medical Association. CMA Policy. Guidelines for Physicians in Interactions with Industry. www.cma.ca

http://policybase.cma.ca/dbtw-wpd/Policypdf/PD08-01.pdf

Swissmedic recommendations:

Concerning the prohibition on promises and acceptance of material benefits under Article 33 of the Therapeutic Products Act, particularly in connection with support provided by the pharmaceutical industry for postgraduate training and continuing education of healthcare professionals (only available in French/German).

http://www.swissmedic.ch/marktueberwachung/00091/00241/01468/index.html?lang=de

Industry codes of conduct:

Code of Conduct of the Pharmaceutical Industry in Switzerland (Pharma Code) of 4 December 2003 (including subsequent revisions)

www.sqci.ch/pluqin/template/sqci/*/63768

Federation of Swiss Medical Devices Trade and Industry Associations (FASMED) Code of Business Conduct

www.fasmed.ch/de/info-center/publikationen/code-of-business-conduct-statuten.html?no cache=1&cid=2601&did=1876&sechash=47098dea

European Federation of Pharmaceutical Industries and Associations (EFPIA) EFPIA HCP Code: EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals

www.efpia.eu/sites/efpiaweb.voxteneo.com/files/EFPIA%20Code Promotion HCP - 11.06.14 FINAL EDITING 07-08-11-mcp-20110630-002-EN-v1 0.pdf

Eucomed Guidelines on Interactions with Healthcare Professionals www.eucomed.org/key-themes/ethics

III. Acceptance of payments in cash or in kind

Relevant legal provisions:

Art. 33 of the Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act; HMG)

Art. 322^{ter} ff. of the Swiss Criminal Code of 21 December 1937 (StGB)

Art. 56 para. 3 of the Federal Act of 18 March 1994 on Health Insurance (KVG)

Information on the preparation of the Guidelines

These SAMS Guidelines come into force on 1.2.2013, superseding the version issued in 2006.

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